

APR 29 1999



UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

Paul E. White, Jr.
Pillsbury Madison & Sutro, LLP
Cushman Darby & Cushman, Intellectual Property Group
1100 New York Ave., N.W.
Ninth Floor, East Tower
Washington, D.C. 20005-3918

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,290,962

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,290,962, which claims the human drug product PANDEL Cream (hydrocortisone buteprate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of July 16, 1998 (63 Fed. Reg. 38410). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3,078) + 1,087 \\ &= 2,626 \text{ days (7.19 years)}\end{aligned}$$

Since the regulatory review period began October 6, 1985, after the patent issue date (September 22, 1981), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued before the date of enactment (September 24, 1984) of 35 U.S.C. § 156 and the request for an exemption under subsection 505(i) of the Federal Food, Drug and Cosmetic Act was not made until after the date of enactment. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of five years.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

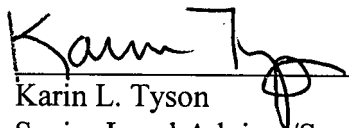
U.S. Patent No.:	4,290,962
Granted:	September 22, 1981
Original Expiration Date:	March 26, 1999
Applicant:	Yasuhide Tachi et al.
Owner of Record:	Taisho Pharmaceutical Co., Ltd.
Title:	Novel Hydrocortisone Derivative
Classification:	552/577
Product Trade Name:	PANDEL Cream (hydrocortisone buteprate)
Term Extended:	Five Years

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


Karin L. Tyson
Senior Legal Advisor/Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: PANDEL CREAM
FDA Docket No.: 97E-0271